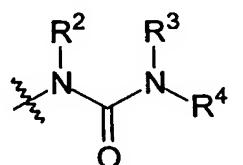
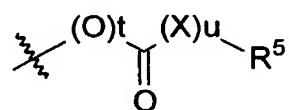


## CLAIMS:

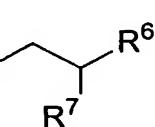
1. A composition for delivering an active agent to a biological system, the composition including a lyotropic phase and an active agent, wherein the  
 5 lyotropic phase is formed from a surfactant that contains a head group selected from the group consisting of any one of structures (I) to (VII):



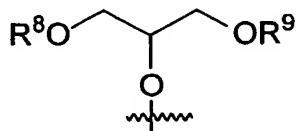
(I)



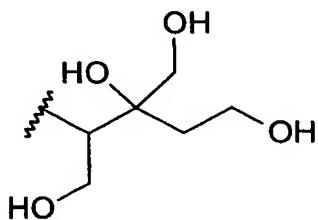
(II)



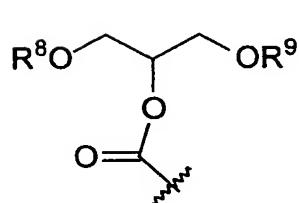
(III)



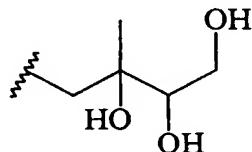
(IV)



(V)



(VI)



(VII)

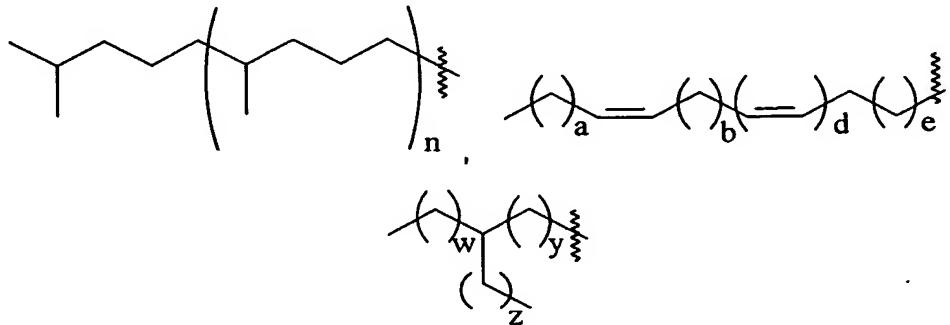
10

and a tail selected from the group consisting of a branched optionally substituted alkyl chain, a branched optionally substituted alkyloxy chain, or an optionally substituted alkenyl chain, and wherein  
 15

- in structure (I)       $R^2$  is  $-H$ ,  $-CH_2CH_2OH$  or another tail group as defined herein,  
 $R^3$  and  $R^4$  are independently selected from one or more of  
 $-H$ ,  $-C(O)NH_2$ ,  $-CH_2CH_2OH$ , or  $-CH_2CH(OH)CH_2OH$
- 5    in structure (II)       $X$  is O, S or N,  
 $t$  and  $u$  are independently 0 or 1,  
 $R^5$  is  $-C(CH_2OH)_2alkyl$ ,  $-CH(OH)CH_2OH$ ,  
 $-CH_2CH(OH)CH_2OH$  (provided the tail group is not oleyl),  
 $-CH_2COOH$ ,  $-C(OH)_2CH_2OH$ ,  $-CH(CH_2OH)_2$ ,
- 10                           $-CH_2(CHOH)_2CH_2OH$ , or  $-CH_2C(O)NHC(O)NH_2$ ,
- in structure (III)       $R^6$  is  $-H$  or  $-OH$ ,  
 $R^7$  is  $-CH_2OH$  or  $-CH_2NHC(O)NH_2$ , and
- in structure (IV) and (VI)       $R^8$  is  $-H$  or  $-alkyl$ ,  
 $R^9$  is  $-H$  or  $-alkyl$ ,
- 15                          and wherein release of the active agent in the biological system is modified by the lyotropic phase.

2.    A composition as in claim 1 wherein the tail is selected from:

20

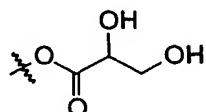


wherein  $n$  is an integer from 2 to 6,  $a$  is an integer from 1 to 12,  $b$  is an integer from 0 to 10,  $d$  is an integer from 0 to 3,  $e$  is an integer from 1 to 12,  $w$  is an integer from 2 to 10,  $y$  is an integer from 1 to 10 and  $z$  is an integer from 2 to 10.

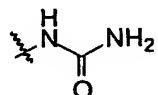
3. A composition as in claim 2 wherein the tail is selected from the list consisting of hexahydrofarnesane ((3,7,11-trimethyl)dodecane), phytane ((3,7,11,15-tetramethyl)hexadecane), oleyl (octadec-9-enyl) and linoleyl (octadec-9,12-dienyl) chains.

5

4. A composition as in claim 1 wherein the head group is:

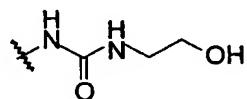


5. A composition as in claim 1 wherein the head group is:



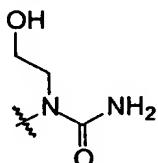
10

6. A composition as in claim 1 wherein the head group is:



15

7. A composition as in claim 1 wherein the head group is:



8. A composition as in claim 1 wherein the lyotropic phase is a reverse hexagonal phase.

20

9. A composition as in claim 1 wherein the active agent is a pharmaceutically active agent.

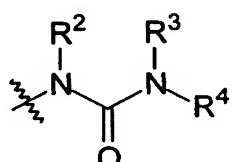
10. A composition as in claim 9 wherein the composition is incorporated into an injectable dosage form.

11. A composition as in claim 9 wherein the composition is incorporated into  
5 an oral dosage form.

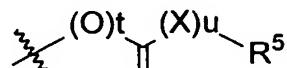
12. A composition as in claim 1 wherein the composition further includes an adjunct vehicle for modifying the release of the active agent, wherein the release profile of the active agent from the adjunct vehicle is different to the  
10 release profile of the active agent from the lyotropic phase.

13. A composition as in claim 12 wherein the adjunct vehicle is a surfactant that forms a second lyotropic phase.

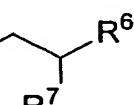
15 14. A composition including an active agent and a surfactant that contains a head group selected from the group consisting of any one of structures (I) to (VII):



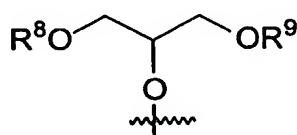
(I)



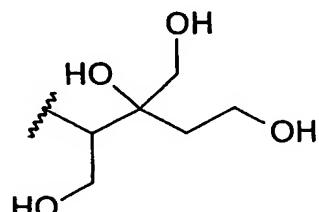
(II)



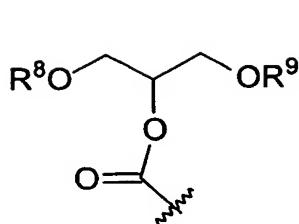
(III)



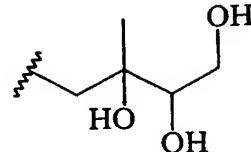
(IV)



(V)



(VI)



(VII)

and a tail selected from the group consisting of a branched optionally substituted alkyl chain, a branched optionally substituted alkyloxy chain, or an

5       optionally substituted alkenyl chain, and wherein

in structure (I)       $\text{R}^2$  is  $-\text{H}$ ,  $-\text{CH}_2\text{CH}_2\text{OH}$  or another tail group as defined herein,

$\text{R}^3$  and  $\text{R}^4$  are independently selected from one or more of  
 $-\text{H}$ ,  $-\text{C}(\text{O})\text{NH}_2$ ,  $-\text{CH}_2\text{CH}_2\text{OH}$ , or  $-\text{CH}_2\text{CH}(\text{OH})\text{CH}_2\text{OH}$

10      in structure (II)       $\text{X}$  is O, S or N,

$\text{t}$  and  $\text{u}$  are independently 0 or 1,

$\text{R}^5$  is  $-\text{C}(\text{CH}_2\text{OH})_2$ alkyl,  $-\text{CH}(\text{OH})\text{CH}_2\text{OH}$ ,

$-\text{CH}_2\text{CH}(\text{OH})\text{CH}_2\text{OH}$  (provided the tail group is not oleyl),

$-\text{CH}_2\text{COOH}$ ,  $-\text{C}(\text{OH})_2\text{CH}_2\text{OH}$ ,  $-\text{CH}(\text{CH}_2\text{OH})_2$ ,

$-\text{CH}_2(\text{CHOH})_2\text{CH}_2\text{OH}$ , or  $-\text{CH}_2\text{C}(\text{O})\text{NHC}(\text{O})\text{NH}_2$ ,

15

in structure (III)       $\text{R}^6$  is  $-\text{H}$  or  $-\text{OH}$ ,

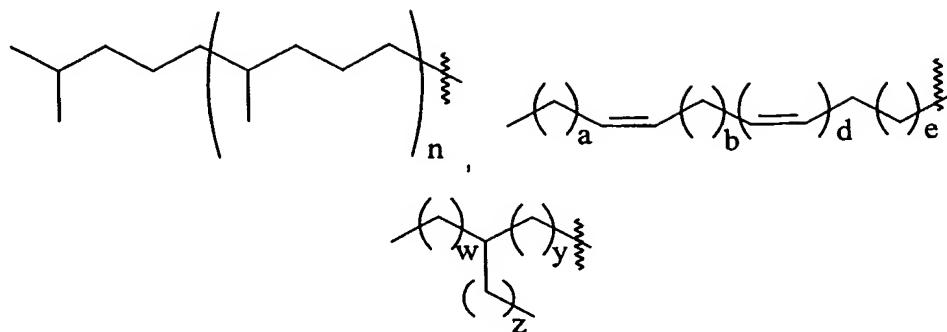
$\text{R}^7$  is  $-\text{CH}_2\text{OH}$  or  $-\text{CH}_2\text{NHC}(\text{O})\text{NH}_2$ , and

in structure (IV) and (VI)       $\text{R}^8$  is  $-\text{H}$  or  $-\text{alkyl}$ ,

$\text{R}^9$  is  $-\text{H}$  or  $-\text{alkyl}$ ,

20      and wherein the surfactant forms a lyotropic phase and release of the active agent to a biological system is modified by the lyotropic phase.

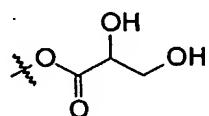
15.      A composition as in claim 14 wherein the tail is selected from:



wherein n is an integer from 2 to 6, a is an integer from 1 to 12, b is an integer  
5 from 0 to 10, d is an integer from 0 to 3, e is an integer from 1 to 12, w is an  
integer from 2 to 10, y is an integer from 1 to 10 and z is an integer from 2 to 10.

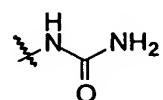
16. A composition as in claim 15 wherein the tail is selected from the list  
consisting of hexahydrofarnesane ((3,7,11-trimethyl)dodecane), phytane  
10 ((3,7,11,15-tetramethyl)hexadecane), oleyl (octadec-9-enyl) and linoleyl  
(octadec-9,12-dienyl) chains.

17. A composition as in claim 14 wherein the head group is:

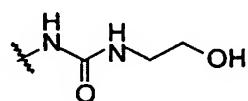


15

18. A composition as in claim 14 wherein the head group is:

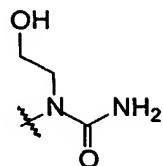


19. A composition as in claim 14 wherein the head group is:



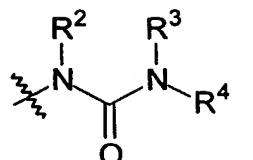
20

20. A composition as in claim 14 wherein the head group is:

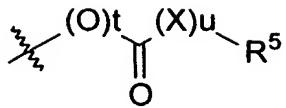


21. A composition as in claim 14 wherein the lyotropic phase is a reverse hexagonal phase.
- 5
22. A composition as in claim 14 wherein the active agent is a pharmaceutically active agent.
23. A composition as in claim 22 wherein the composition is incorporated into  
10 an injectable dosage form.
24. A composition as in claim 22 wherein the composition is incorporated into an oral dosage form.
- 15 25. A composition as in claim 14 wherein the composition further includes an adjunct vehicle for modifying the release of the active agent, wherein the release profile of the active agent from the adjunct vehicle is different to the release profile of the active agent from the lyotropic phase.
- 20 26. A modified release composition as in claim 25 wherein the adjunct vehicle is a surfactant that forms a second lyotropic phase.
27. A method for modifying the release of an active agent in a biological system, the method including the steps of:
- 25 a) providing a composition containing the active agent and a lyotropic phase that is formed from a surfactant that contains a head group selected from the group consisting of any one of structures (I) to (VII):

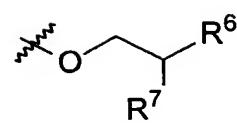
- 70 -



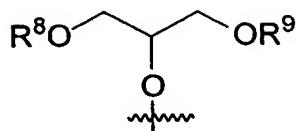
(I)



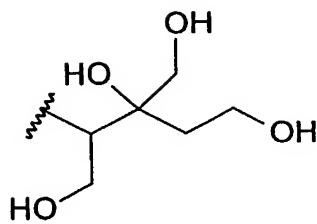
(II)



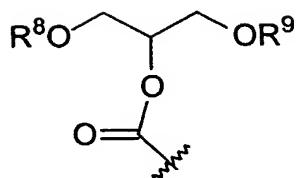
(III)



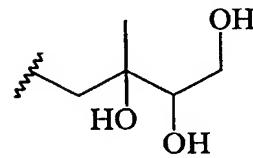
(IV)



(V)



(VI)



(VII)

5

and a tail selected from the group consisting of a branched optionally substituted alkyl chain, a branched optionally substituted alkyloxy chain, or an optionally substituted alkenyl chain, and wherein

- 10 in structure (I) R<sup>2</sup> is -H, -CH<sub>2</sub>CH<sub>2</sub>OH or another tail group as defined herein,  
R<sup>3</sup> and R<sup>4</sup> are independently selected from one or more of  
-H, -C(O)NH<sub>2</sub>, -CH<sub>2</sub>CH<sub>2</sub>OH, or -CH<sub>2</sub>CH(OH)CH<sub>2</sub>OH
- in structure (II) X is O, S or N,  
t and u are independently 0 or 1,  
R<sup>5</sup> is -C(CH<sub>2</sub>OH)<sub>2</sub>alkyl, -CH(OH)CH<sub>2</sub>OH,  
-CH<sub>2</sub>CH(OH)CH<sub>2</sub>OH (provided the tail group is not oleyl),
- 15

-CH<sub>2</sub>COOH, -C(OH)<sub>2</sub>CH<sub>2</sub>OH, -CH(CH<sub>2</sub>OH)<sub>2</sub>,  
-CH<sub>2</sub>(CHOH)<sub>2</sub>CH<sub>2</sub>OH, or -CH<sub>2</sub>C(O)NHC(O)NH<sub>2</sub>,

in structure (III) R<sup>6</sup> is -H or -OH,

R<sup>7</sup> is -CH<sub>2</sub>OH or -CH<sub>2</sub>NHC(O)NH<sub>2</sub>, and

5 in structure (IV) and (VI) R<sup>8</sup> is -H or -alkyl,

R<sup>9</sup> is -H or -alkyl; and

b) exposing the composition to the biological system so that the active agent is released into the biological system and said release is modified by the lyotropic phase.

10

28. A method for modifying the release of an active agent as in claim 27 wherein the lyotropic phase is a reverse hexagonal phase.

15

29. A method for modifying the release of an active agent as in claim 27 wherein said modified release is sustained release.

30. A method for modifying the release of an active agent as in claim 27 wherein said modified release is multiphase release..

20

31. A method for modifying the release of an active agent as in claim 27 wherein said modified release provides for an improved bioavailability of the active agent in the biological system.

25

32. A method for modifying the release of an active agent as in claim 27 wherein the method includes a step of forming the lyotropic phase prior to introducing the composition to the biological system.

30

33. A method for modifying the release of an active agent as in claim 27 wherein the method includes a step of introducing a precursor composition containing the surfactant and the active agent to the biological system so that the lyotropic phase is formed *in situ*.

34. A method for modifying the release of an active agent as in either claim 32 or claim 33 wherein the method includes the steps of incorporating the composition into an injectable dosage form, and injecting the composition into the biological system.

5

35. A method for modifying the release of an active agent as in either claim 32 or claim 33 wherein the method includes the steps of incorporating the composition into an oral dosage form, and orally administering the composition to the biological system.

10

36. A method for modifying the release of an active agent as in claim 27 wherein the method includes the step of introducing an adjunct vehicle for modifying the release of the active agent into the composition.

15

37. A method for modifying the release of an active agent as in claim 27 wherein the method includes the step of introducing a second lyotropic phase for modifying the release of the active agent into the composition.

20

38. A method of forming a sustained release deposit *in situ* in a biological system, the method including the step of introducing a bolus of the composition of claim 1 in the biological system, or forming a bolus of the composition of claim 1 in the biological system.

25

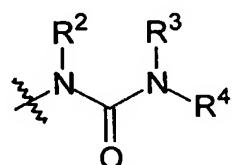
39. A method for modifying the release of a biologically active agent in an animal, the method including the step of exposing a composition containing a lyotropic phase formed from a surfactant and the biologically active agent to the gastrointestinal tract of the animal, wherein the surfactant is not glyceryl monooleate or glyceryl monolinoleate.

30

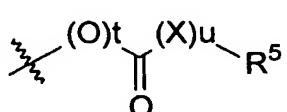
40. A method for modifying the release of a biologically active agent as in claim 39 wherein the lyotropic phase is a reverse hexagonal phase.

41. A method for modifying the release of a biologically active agent in an animal as in claim 39, wherein the lyotropic phase is formed from a surfactant that contains a head group selected from the group consisting of any one of structures (I) to (VII):

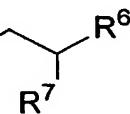
5



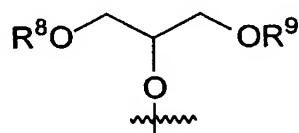
(I)



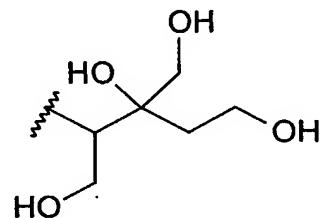
(II)



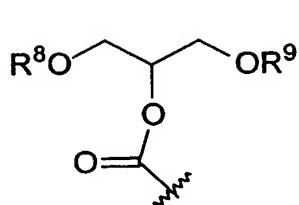
(III)



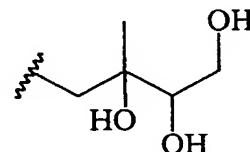
(IV)



(V)



(VI)



(VII)

10

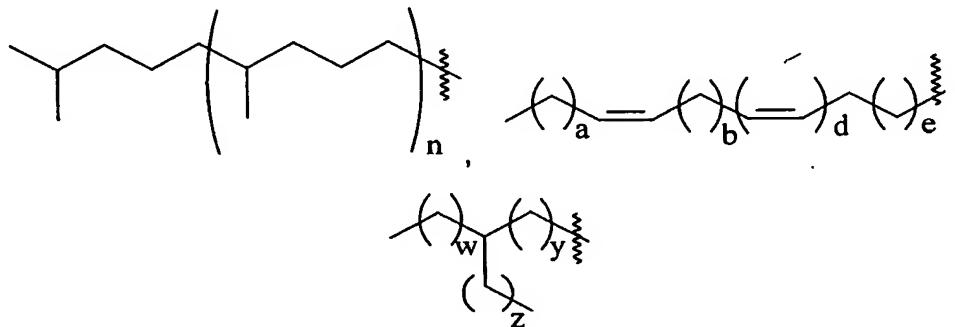
and a tail selected from the group consisting of a branched optionally substituted alkyl chain, a branched optionally substituted alkyloxy chain, or an optionally substituted alkenyl chain, and wherein

15 in structure (I)  $R^2$  is  $-H$ ,  $-CH_2CH_2OH$  or another tail group as defined herein,  
 $R^3$  and  $R^4$  are independently selected from one or more of

- H, -C(O)NH<sub>2</sub>, -CH<sub>2</sub>CH<sub>2</sub>OH, or -CH<sub>2</sub>CH(OH)CH<sub>2</sub>OH
- in structure (II)      X is O, S or N,  
                         t and u are independently 0 or 1,  
                         R<sup>5</sup> is -C(CH<sub>2</sub>OH)<sub>2</sub>alkyl, -CH(OH)CH<sub>2</sub>OH,  
 5                        -CH<sub>2</sub>CH(OH)CH<sub>2</sub>OH (provided the tail group is not oleyl),  
                         -CH<sub>2</sub>COOH, -C(OH)<sub>2</sub>CH<sub>2</sub>OH, -CH(CH<sub>2</sub>OH)<sub>2</sub>,  
                         -CH<sub>2</sub>(CHOH)<sub>2</sub>CH<sub>2</sub>OH, or -CH<sub>2</sub>C(O)NHC(O)NH<sub>2</sub>,
- in structure (III)      R<sup>6</sup> is -H or -OH,  
                         R<sup>7</sup> is -CH<sub>2</sub>OH or -CH<sub>2</sub>NHC(O)NH<sub>2</sub>, and
- 10    in structure (IV) and (VI)    R<sup>8</sup> is -H or -alkyl,  
                         R<sup>9</sup> is -H or -alkyl.

42. A method for modifying the release of a biologically active agent in an animal as in claim 41, wherein the tail is selected from:

15



- wherein n is an integer from 2 to 6, a is an integer from 1 to 12, b is an integer  
 20 from 0 to 10, d is an integer from 0 to 3, e is an integer from 1 to 12, w is an integer from 2 to 10, y is an integer from 1 to 10 and z is an integer from 2 to 10.

43. A method for modifying the release of a biologically active agent in an animal as in claim 42, wherein the tail is selected from the list consisting of  
 25 hexahydrofarnesane ((3,7,11-trimethyl)dodecane), phytane ((3,7,11,15-tetramethyl)hexadecane), oleyl (octadec-9-enyl) and linoleyl (octadec-9,12-dienyl) chains.

44. A method for modifying the release of a biologically active agent in an animal as in claim 41, wherein the lyotropic phase is a reverse hexagonal phase.

5

45. A method for modifying the release of an active agent as in claim 39 wherein said modified release is sustained release.

46. A method for modifying the release of an active agent as in claim 39  
10 wherein said modified release is multiphase release.

47. A method for modifying the release of an active agent as in claim 39 wherein said modified release provides for an improved bioavailability of the active agent in the gastrointestinal tract.

15

48. A method for modifying the release of an active agent as in claim 39 wherein the method includes a step of forming the lyotropic phase prior to exposing the composition to the gastrointestinal tract.

20 49. A method for modifying the release of an active agent as in claim 39 wherein the method includes a step of introducing a precursor composition containing the surfactant and the active agent to the gastrointestinal tract so that the lyotropic phase is formed *in situ*.

25 50. A method for modifying the release of an active agent as in claim 48 wherein the method includes the steps of incorporating the active agent and the lyotropic phase into an oral dosage form, and orally administering the composition to the animal.

30 51. A method for modifying the release of an active agent as in claim 49 wherein the method includes the steps of incorporating the active agent and the

surfactant into an oral dosage form, and orally administering the composition to the animal.

52. A method for modifying the release of an active agent as in claim 39  
5 wherein the method includes the step of introducing an adjunct vehicle for  
modifying the release of the active agent into the composition.

53. A method for modifying the release of an active agent as in claim 39  
wherein the method includes the step of introducing a second lyotropic phase  
10 for modifying the release of the active agent into the composition.

54. A modified release composition according to claim 1 and substantially as  
hereinbefore described with reference to the accompanying examples.

15 55. A composition according to claim 14 and substantially as hereinbefore  
described with reference to the accompanying examples.

56. A method for modifying the release of an active agent in a biological  
system according to claim 27 and substantially as hereinbefore described with  
20 reference to the accompanying examples.

57. A method for modifying the release of a biologically active agent in an  
animal according to claim 39 and substantially as hereinbefore described with  
reference to the accompanying examples.